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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,194	08/15/2002	Michel Renard	218874USOPCT	8696

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
01/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/030,194	RENARD ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appeal Brief filed on 3/7/2008 & 4/24/2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638

2. Claims 1, 4-8 and 11-16 are pending.

Claims 2-3 and 9-10 have been canceled.

3. Claims 1, 4-8 and 11-16 including SEQ ID NO:5, 7 and 4 are examined in the present office action.

4. Rejections and objections not set forth below are withdrawn.

Claim Objection

5. Claim 16 is objected to for including a "(" at the beginning of the sentence.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4-8 and 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid sequence or to a plant with reduced development comprising one or more copies of a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the wild type protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence such that the nucleic acid sequence encodes a mutant protein comprising SEQ ID NO:7 comprising the peptide sequence Gly Tyr X_1 Val Glu X_2 in which X_2 represents a basic amino acid, or wherein the nucleic acid sequence encodes the polypeptide represented by SEQ ID NO:4, or

wherein X_2 represents lysine, or a plant with reduced development comprising one or more copies of a nucleic acid that encodes the polypeptide represented by SEQ ID NO:4.

Because Applicants do not define the term "represent", the Office defines the term according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). The Office interprets claim 4 to read on a large number of nucleic acid sequences because Applicants recite "the polypeptide represented by SEQ ID NO:4" and "represented by SEQ ID NO:4" encompasses a large number of protein sequences; given the above definition.

Applicants isolated their invention from dwarf plants of the "STELLAR" rapeseed line. The DNA sequence comprises 1716 bp coding sequence listed in SEQ ID NO:1 encoding the BZH polypeptide comprising 572 amino acids of SEQ ID NO:2. Applicants disclose the mutant gene contains a G to A substitution at position 1695 which creates a Glu to Lys amino acid change at position 546, whose sequences are set forth in SEQ ID NO:3 and 4, respectively (pages 7-8, Example 1).

Applicants do not disclose a representative number of sequences encoding a plant protein of the GRAS family comprising SEQ ID NO:7 in which the second glutamic acid is changed to a basic amino acid nor do Applicants describe structural features of the claimed six amino acid domain that are required for the activity of the domain or structural features that are required of the entire protein so that when SEQ ID NO:7 is present in the protein, a plant transformed with a nucleic acid encoding said protein exhibits a dwarf phenotype.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides that encode an amino acid sequence comprising SEQ ID NO:7 in which the second glutamic acid is changed to any basic amino acid and wherein a plant transformed with the polynucleotide exhibits a reduction in plant size as compared to a wild type plant. Applicants only describe a single sequence of SEQ ID NO:4 in which SEQ ID NO:7 comprises a lysine in place of the second glutamic acid and wherein SEQ ID NO:4 is encoded by SEQ ID NO:3. Furthermore, Applicants fail to describe a structure/function relationship between the domain of SEQ ID NO:7 and a dwarf phenotype. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the amino acid

sequence of SEQ ID NO:7, it remains unclear what features identify a protein comprising the amino acid sequence of SEQ ID NO:7 that when transformed into a plant result in a dwarf phenotype. Since the genus of proteins comprising SEQ ID NO:7 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 5-8, 11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Foisset et al (1995, Theor. Appl. Genet. 91(5):756-761, listed in the IDS) taken with the evidence of Barret et al (1998, Theor. Appl. Genet. 97:828-833).

The claims are drawn to a plant with reduced development comprising one or more copies of a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the wild type protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence such that the nucleic acid sequence encodes a mutant protein comprising SEQ ID NO:7 comprising the peptide sequence Gly Tyr X_1 Val Glu X_2 in which X_2 represents a basic amino acid, or wherein the plant is a crucifer, or wherein the plant is rapeseed, or wherein X_2 represents lysine, or wherein said plant is obtained by chemical mutagenesis, or a descendant of said plant comprising one or more copies of said nucleic acid sequence, or a plant with reduced development comprising one or more copies of a nucleic acid that encodes the polypeptide represented by SEQ ID NO:4.

Foisset et al disclose a dwarf Brassica napus plant comprising a mutant *breizh* (*bzh*) gene obtained by chemical mutagenesis (page 756, right column, 1st full paragraph). Because of Applicants' admitted statement "The inventors have now characterized and sequenced the *BZH* gene of *B. napus*, and its mutant allele *bzh*, associated with the dwarf phenotype previously observed by Foisset et al (1995, …) (page 3, lines 30-33), the Office contends Foisset et al disclose a plant with said mutant gene. In particular, Foisset et al disclose a rapseed plant, that is a crucifer, or descendants of said plant comprising the mutant bzh gene (page 757, left column, 2nd full paragraph). Barret et al teach that the *Bzh* gene is semi-dominant by stating "…and heterozygous (semidwarf; *Bzh/bzh*) plants…" (page 828, right column, top paragraph). The Office contends the instant application appears to merely be a further characterization of plants containing the same genetic locus as the prior art plants. See *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202, (Fed. Cir. 2002), which teaches that newly recognized constituents or properties of a prior art product are inherent properties which do not render claims to that product patentable, and as such, Foisset et al anticipate the claimed invention.

Applicant's arguments filed in the Appeal Brief filed 3/7/2008 have been fully considered but they are not persuasive.

Applicants contend the Examiner has not explained how Foisset et al provide an enabling disclosure of this mutant plant (page 7 of Appeal Brief, 4th full paragraph). Applicants contend Foisset et al disclose that the mutation is the result of EMS and Applicants contend that one of skill in the art would have to perform many procedures to end up with a plant in which the BZH gene is mutated, given all the possible genes that could be mutated and produce a dwarf plant (paragraph bridging pages 7 and 8 of Appeal Brief). Applicants contend Barret et al further

disclose that the bzh mutation is semi-dominant and Applicants contend the semi-dominant nature of the mutation would further complicate producing such a plant (page 8 of Appeal Brief, 1st full paragraph). Applicants contend one of skill in the art will not be able to determine if they are in possession of a plant whose bzh mutation is the same as Applicants' (page 8 of Appeal Brief, bottom paragraph). Applicants contend the Examiner has not met the burden of demonstrating that the allegedly inherent characteristic of the invention flows from the teachings of the applied prior art (page 9 of Appeal Brief, 2nd paragraph). Lastly, Applicants contend EMS is a non-discriminatory mutagen and the disclosure of Foisset et al would not place the skilled artisan in possession of the specific bzh mutant plant (page 9 of Appeal Brief, bottom paragraph).

The Office contends the claims are drawn to a plant having reduced development comprising the nucleic acid sequence of claim 1. Foisset et al teach a mutant Brassica napus plant having a reduced development wherein the reduced development or dwarf phenotype is the result of the mutant bzh gene. Foisset et al state "The dwarf Bzh line called 'B192' originated from the 'Primor' cultivar through chemical mutagenesis on seeds (MSE 0.50%). 'B192' was first crossed with the 'Jet Neuf' cultivar and the Bzh gene was then introduced into different rapeseed line..." (page 757 of Foisset et al, "Material' and methods" 1st paragraph). Therefore, Foisset et al possess seeds of plants that comprise the mutant bzh gene. The Office contends the claims are enabled because Applicants state "The inventors have now characterized and sequenced the *BZH* gene of *B. napus*, and its mutant allele *bzh*, associated with the dwarf phenotype previously observed by Foisset et al (1995, …) (page 3, lines 30-33). Therefore the Office contends if a skilled artisan wants a plant with the mutant bzh gene, they can contact Foisset et al and request

seeds comprising the mutant gene. It is known in the art that plant material disclosed in a published paper is available to the public upon request. One of skill in the art would not have to recreate the mutant bzh gene. The Office contends a plant comprising the mutant sequence of Applicants' was available to the public more than one year prior to Applicants' priority date. See MPEP 2121.03 where it states that a publication disclosing a cotton cultivar had an enabling disclosure because one of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 4-8, 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foisset et al (1995, Theor. Appl. Genet. 91(5):756-761, listed in the IDS) taken with the evidence of Barret et al (1998, Theor. Appl. Genet. 97:828-833).

The claims are drawn to an isolated nucleic acid sequence or to a plant with reduced development comprising one or more copies of a nucleic acid sequence obtained by mutation of a sequence encoding a plant protein of the GRAS family, wherein the wild type protein comprises the peptide sequence Gly Tyr X_1 Val Glu Glu of SEQ ID NO:5 in which X_1 represents arginine or asparagines wherein said mutation results in a modification of said sequence such

that the nucleic acid sequence encodes a mutant protein comprising SEQ ID NO:7 comprising the peptide sequence Gly Tyr X_1 Val Glu X_2 in which X_2 represents a basic amino acid, or wherein the nucleic acid sequence encodes the polypeptide represented by SEQ ID NO:4, or wherein the plant is a crucifer, or wherein the plant is rapeseed, or wherein X_2 represents lysine, or wherein said plant is obtained by chemical mutagenesis, or a descendant of said plant comprising one or more copies of said nucleic acid sequence, or a plant with reduced development comprising one or more copies of a nucleic acid that encodes the polypeptide represented by SEQ ID NO:4.

Because Applicants do not define the term "represent", the Office defines the term according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). The Office interprets claim 4 to read on a large number of nucleic acid sequences because Applicants recite "the polypeptide represented by SEQ ID NO:4" and "represented by SEQ ID NO:4" encompasses a large number of protein sequences; given the above definition.

The teachings of Foisset et al taken with the evidence of Barret et al have been discussed above.

Foisset et al taken with the evidence of Barret et al do not teach the claimed isolated nucleic acid sequence, or wherein the sequence encodes the polypeptide represented by SEQ ID NO:4.

Given the recognition of those of ordinary skill in the art of the value of breeding dwarf plants by introducing the Bzh mutant gene into breeding lines using marker assisted breeding as

taught by Foisset et al, it would have been obvious to one of ordinary skill in the art to use the method of Foisset et al of introducing the mutant Bzh gene into breeding lines and to modify the method of Foisset et al of selecting plants comprising the mutant Bzh gene using markers by cloning the mutant Bzh gene. Motivation to clone the Bzh gene is disclosed by Foisset et al who state, "This work represents the first step towards a better understanding of the dwarf mutation, the development of marker-assisted selection, and the cloning of the underlying gene responsible for dwarfing" (abstract, last sentence). Additional motivation comes from Barret et al who state "For instance, we can now imagine the selection at an early developmental stage of homozygous *bzh/bzh* dwarf plants in BnF2 progeny in order to individually increase seeds of each selected plant under a small cage before field tests. For optimal selection of the dwarf character, the gene has to be cloned" (page 833, left column).

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
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